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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,343	07/30/2003	Tsann-Long Su	08919-094001 / 12A-910910	9319
26161	7590	04/14/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			AULAKH, CHARANJIT	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/630,343	Applicant(s) SU, TSANN-LONG	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 10, 13, 22 and 28-35 is/are rejected.
- 7) ☒ Claim(s) 4-7, 9, 11, 12, 14-21 and 23-27 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Claims 1-35 are pending in the application.

Claim Objections

2. Claims 29-32 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in alternate only. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating breast cancer, does not reasonably provide enablement for treating all types of cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see *Ex parte Foreman*, 230 USPQ at 547; *Wands*, In re, 858 F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least

four of the above mentioned eight factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, the predictability or unpredictability and the breadth of claims.

The instant compounds reduce tumor volume by about 80% in nude mice bearing human breast tumor MX-1 xenograft following their in vivo administration as shown in example 18 on page 19 and therefore, will have utility in treating breast cancer. The specification teaches that the effects of instant compounds on cell growth were determined on all human tumor cells in vitro (see example 16 on page 18). However, there is no indication regarding the results obtained from this study. In the same example, the specification teaches that compounds 1-6 were tested on five human tumor cell lines and at least one cell line was significantly responsive to cytotoxic effect of the instant compounds as compared to known prior art compounds. Again, there is no teaching what five different tumor cell lines were used and which cell line was found to be responsive to all the compounds tested. It is clear from these in vitro experiments that there is lot of unpredictability since only one tumor cell line was found to be more responsive to the instant compounds compared to known prior art compounds. It is also well known in the art that activity in vitro does not always correlate with in vivo activity. There are no working examples present showing efficacy of the instant compounds in vivo animal models of all types of cancers. The instant compounds of formula (I) encompass hundreds of thousands of compounds based on variables R1-R6, m and n and therefore, in absence of such teachings, guidance or presence of working examples, it would require undue experimentation to demonstrate the effectiveness of

the instant compounds in known animal models of all types of cancers and hence their utility for treating all types of cancers.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 28-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29-32 depend upon claim 28. In claim 28, compound of formula (I) is mentioned.

However, this formula (I) is not present in claim 28.

Claim 34 depends upon claim 33. In claim 33, compound of formula (I) is mentioned.

However, this formula (I) is not present in claim 33.

In claim 33, the term --- cancer--- is indefinite since specific type of cancer is not defined.

Claim 35 is directed to a method of synthesizing compound of formula (II) by reacting a compound of formula (III) with a compound of formula (IV). However, this reaction forms a compound of formula (IV) as mentioned in line 116 on page 24. Should it be formula (II) in line 116?

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 1-3, 8, 10, 13, 22, 28, 30, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Denny (J. Med. Chem., cited on applicants form 1449).

Denny discloses potential antitumor agents. The compound no. 79 (see table 1 on page 279) disclosed by Denny anticipates the instant claims when R1 represents H, R4 represents CH3 and both m and n are 0 in the instant compounds of formula (I).

It is of note that the applicants have put a proviso to exclude this compound. However, this proviso does not exclude this compound since even when R5 and R6 both are not hydrogen, both m and n can still be 0.

Allowable Subject Matter

8. Claims 4-7, 9, 11, 12, 14-21 and 23-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. It is of note that the instant claims are anticipated by Chang (Bioorg. & Medicinal Chemistry, vol. 11 (23), pages 4959-4969, 2003). It appears that this reference is applicant's own work and furthermore, is published after the effective filing date of the instant application and therefore, may not constitute a prior art reference under 35 U.S.C. 102(a). The examiner has ordered this publication to verify the publication date of this reference. The applicants are requested to verify this in their response also.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charanjit S. Aulakh
Primary Examiner
Art Unit 1625